BlueCross BlueShield Association

An Association of Independent Blue Cross and Blue Shield Plans

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FDA Acting Commissioner Andrew von Eschenbach, M.D.
Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 2005N-0410; Prescription Drug User Fee Act (PDUFA)

Dear Acting Commissioner von Eschenbach:

On behalf of the 39 independent, locally operated Blue Cross and Blue Shield Plans that collectively provide healthcare coverage to more than 93 million Americans, I am pleased to submit written comments on what features the FDA should propose for the next Prescription Drug User Fee Act (PDUFA) program.

While successful in speeding access to new therapies, the PDUFA program has not had a commensurate effect on improving post-market safety. In the 2002 PDUFA reauthorization, Congress allowed the FDA to use PDUFA program funds for some post-market activities, such as monitoring adverse event reports and disclosing Phase IV study information. However, in 2005 only 2.5% of PDUFA program funds went to the Office of Drug Safety (ODS), the FDA's primary office for post-market safety activities. Moreover, as more new drugs reach the market faster under PDUFA, spending on direct-to-consumer advertising (DTCA) has swelled: from $2.7 billion in 2001 to $4.2 billion today. Yet the FDA devotes less than $1 million a year to reviewing DTCA.

Therefore, BCBSA asks that you consider the following recommendations for expanding safety-related activities under the PDUFA program:

First, increase the portion of PDUFA program funds that is devoted to post-market surveillance. In light of the estimated 770,000 injuries and deaths caused each year by adverse drug events, 2.5% of PDUFA funding for the Office of Drug Safety is too low. Safety oversight of newly approved drugs is integral to drug approval and needs to keep pace with drug approvals. More funding should be devoted to drug safety activities.

Second, expand the definition of user fee-funded activities to include FDA monitoring of risk and benefit information in DTCA. Additional funding will help the FDA ensure that consumers have more complete, accurate, and understandable information about their prescription drugs. FDA's Division of Drug Marketing, Advertising, and Communication (DDMAC) is responsible for implementing FDA's regulations governing direct-to-consumer advertising. DTCA has grown from $2.7 billion in 2001 to $4.2 billion today, yet only seven FDA employees are devoted to this function. As PDUFA speeds new drug approvals, and pharmaceutical manufacturers use DTCA to speed the introduction of new drugs in the market, funding for DTCA oversight needs to be increased. PDUFA user fees should be extended to this function.

Third, require manufacturers to provide comparative information about new drugs that substitute for existing therapies. Comparative information about the benefits, costs, and risks of new drugs would help consumers, and their physicians, make more informed decisions about their medical treatment options. Some new drugs are truly breakthrough products – offering treatment where no effective treatment currently exists, but other newly introduced drugs will simply substitute newer, more expensive drug treatments for existing cost-effective agents. FDA should consider what kind of information could be useful in making evaluations of alternative therapies, and the information should be provided to allow consumers to make value-driven decisions.

Thank you for the opportunity to make these recommendations. PDUFA has improved with each reauthorization and we hope that FDA will take the opportunity to further strengthen and enhance PDUFA and the activities that the program supports. If you have any questions you may contact Nan North at (202) 626-8649.

Sincerely,

Allan Korn, M.D.
Senior Vice President and Chief Medical Officer